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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/043,232

01/14/2002

Krzysztof Chwalisz

SCH 1537 D2

7422

23599

7590

04/22/2005

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EXAMINER

MITCHELL, GREGORY W

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/043,232	CHWALISZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12-14,33-35 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-14,33-35 and 48-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |    |
|---|---|----|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     | RD |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |    |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |    |

### **DETAILED ACTION**

This Office Action is in response to the Remarks, Amendments and Declaration filed January 21, 2005. Claims 53 and 54 have been added. Claims 13 and 34 have been amended. Claims 12-14, 33-35, and 48-54 are pending and are examined herein.

Applicant's arguments are persuasive regarding the 35 USC 112(1) rejection over the term "antiprogesterin" and said rejection is hereby withdrawn. The 35 USC 103 rejections of the previous Office Action are also withdrawn. The following rejections now apply.

#### ***Claim Objections***

Claim 53 is objected to because of the following informalities: there are spelling errors. In the third compound, "cyanphenyl" should be "cyanophenyl". Also in the third compound, "-17b-hydroxy" should be "-17 $\beta$ -hydroxy". Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because claim 53 cites a published document. It is unclear what limitation to the claims Applicant intends by

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including the references into the claim. Claim 54 is rejected for depending from an indefinite claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13, 33-34 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al. (USPN 5470847) in view of Teutsch et al. (USPN 4,447,424).

Garfield et al. teaches a method of contraception comprising the administration of NOS inhibitors (Abstract; col. 1, lines 6-15; col. 3, line 55-col. 4, line 6; col. 4, lines 40-45). L-NAME is disclosed as a preferred NOS inhibitor (col. 4, lines 7-35). The reference does not teach the administration of a NOS inhibitor in combination with an antiprogesterin for contraception.

Teutsch et al. teaches a method of contraception by administration of an agent of the invention in a dosage of 25-200 mg/day (col. 28, lines 30-34). The agents are taught for both anti-implantation and abortive activities (col. 57, line 50-col. 58, line 18). Mifepristone is within the scope of the compounds disclosed and is specifically taught

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as a compound useful in the invention disclosed therein (col. 8, lines 3-59; col. 31, lines 57-59).

It would have been obvious to one of ordinary skill in the art to add the mifepristone of Teutsch et al. to the contraceptive treatment of Garfield et al. because both Teutsch et al. and Garfield et al. are directed to methods of producing contraception and it is well established that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, one would have been motivated by an expectation of similar or improved success in achieving contraception.

Claims 12, 14, 33, 35 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al. (USPN 5470847) in view of Jones et al. (USPN 5462949).

Garfield et al. teaches a method of contraception comprising the administration of NOS inhibitors (Abstract; col. 1, lines 6-15; col. 3, line 55-col. 4, line 6; col. 4, lines 40-45). L-NAME is disclosed as a preferred NOS inhibitor (col. 4, lines 7-35). The reference does not teach the administration of a NOS inhibitor in combination with an antiprogesterin for contraception.

Jones et al. teaches that methods of contraception via the post coital administration of antiprogesterins is well known in the art (col. 1, lines 44-47).

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It would have been obvious to one of ordinary skill in the art to add the antiprogestins, as taught by Jones et al., to the contraceptive treatment of Garfield et al. because both Jones et al. and Garfield et al. are directed to methods of contraception and it is well established that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, one would have been motivated by an expectation of similar or improved success in achieving contraception.

It is also noted that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 12, 33, 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garfield et al. (USPN 5470847) in view of Chwalisz et al. (USPN 5439913).

Garfield et al. teaches a method of contraception comprising the administration of NOS inhibitors (Abstract; col. 1, lines 6-15; col. 3, line 55-col. 4, line 6; col. 4, lines 40-45). L-NAME is disclosed as a preferred NOS inhibitor (col. 4, lines 7-35). The reference does not teach the administration of a NOS inhibitor in combination with an antiprogestin for contraception.

Chwalisz et al. teaches the compounds as instantly claimed as competitive progesterone antagonists useful for contraception (Abstract). Chwalisz et al. teaches the use of the competitive progesterone antagonists as a means of inhibiting the

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implantation of a fertilized egg (col. 2, lines 55-65). It is also taught that at higher dosages, an abortive effect can be achieved (Abstract).

It would have been obvious to one of ordinary skill in the art to add the competitive progesterone antagonists of Chwalisz et al. to the contraceptive treatment of Garfield et al. because both Chwalisz et al. and Garfield et al. are directed to methods of contraception and it is well established that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, one would have been motivated by an expectation of similar or improved success in achieving contraception.

It is also noted that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

### ***Response to Arguments***

Applicant's arguments filed January 21, 2005 have been fully considered but they are not persuasive. Applicant's arguments that the two teachings operate via a different mechanism are not persuasive. The field of endeavor for the teaching references is the same, namely a method of contraception. The fact that the teachings operate via a different mechanism provides more motivation to combine, not less, because there

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would be an expectation of providing enhanced results by simultaneously solving a single problem in more than one manner.

Applicant's arguments as they pertain to the declaration are not persuasive for the reasons given below.

### ***Response to Amendment***

The declaration under 37 CFR 1.132 filed January 21, 2005 is insufficient to overcome the rejection of claims 12-14, 33-35, and 48 based upon the 35 USC 103 rejection over Garfield et al. in view of Teutsch et al. as set forth in the last Office action because: the declaration is not commensurate with the scope of the claims. Applicant has shown experimental results comprising only a pair of NOS inhibitors and a single antiprogestin. The scope of the claims is broad in that it encompasses *all* NOS inhibitors and *all* antiprogestins. The showing of unexpected results with a pair of NOS inhibitors in combination with a single antiprogestin is insufficient to overcome the instant rejections.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone



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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

A handwritten signature in black ink, appearing to read 'S. Padmanabhan', with a horizontal line underneath the name.

SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER